SUBSTITUTE FORM PTO-1449 (MODIFIED)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

Attorney Docket No. 50

50164/026005

PATENT AND TRADEMARK OFFICE

Serial No. 10/777,517

Jost-Price et al.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)

Filing Date

Applicant

February 12, 2004

Group

1614

(37 C.F.R. § 1.98(b))

**IDS Filed** 

December 20, 2007

Examiner's Initials	Document Number	Publication Date	Patentee or Applicant	Class	Subclass	Filing Date (If Appropriate)
*	4,034,087	Jul. 5, 1977	Voorhees			
	4,107,306	Aug. 15, 1978	Voorhees			
	4,229,449	Oct. 21, 1980	Melloni et al.			
	4,721,723	Jan. 26, 1988	Barnes et al.			
	4,727,064	Feb. 23, 1998	Pitha			
	4,775,667	Oct. 4, 1988	Saitoh et al.			
	4,804,669	Feb. 14, 1989	Lassen			
	4,956,388	Sep. 11, 1990	Robertson et al.			
	5,007,790	Apr. 16, 1991	Shell et al.			
	5,061,728	Oct. 29, 1991	Koe			
	5,248,699	Sep. 28, 1993	Sysko et al.			
	5,368,861	Nov. 29, 1994	Ushimaru et al.			
	5,502,080	Mar. 26, 1996	Hitzig			
	5,618,563	Apr. 8, 1997	Berde et al.			
	5,637,314	Jun. 10, 1997	Sharpe et al.			
	5,672,612	Sep. 30, 1997	Ronsen et al.			
•	5,688,808	Nov. 18, 1997	Jones et al.			
	5,688,810	Nov. 18, 1997	Jones et al.			
	5,693,646	Dec. 2, 1997	Jones et al.			
	5,693,647	Dec. 2, 1997	Jones et al.			
-	5,696,127	Dec. 9, 1997	Jones et al.			

## **EXAMINER**

DATE CONSIDERED

SUBSTITUTE FORM PTO-1449			50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
INFORMATI	ON DISCLOSURE	Applicant	Jost-Price et al.
STATEMEN	ON DISCLOSURE T BY APPLICANT Shoots if pacassan)	Filing Date	February 12, 2004
(Use several sheets if necessary)		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

5,696,128	Dec. 9, 1997	Cincotta et al.		
5,696,130	Dec. 9, 1997	Jones et al.		
5,696,133	Dec. 9, 1997	Jones et al.		
5,700,485	Dec. 23, 1997	Berde et al.		
5,734,083	Mar. 31, 1998	Wilson et al.		
5,773,478	Jun. 30, 1998	Richards et al.		
5,792,476	Aug. 11, 1998	Hällgren		
5,811,436	Sep. 22, 1998	Leonard et al.	,	
5,872,127	Feb 16, 1999	Cincotta et al.		
5,872,132	Feb. 16, 1999	Ward et al.		
5,874,447	Feb. 23, 1999	Benneker et al.		
5,900,249	May 4, 1999	Smith		
5,900,423	May 4, 1999	Ward et al.		
5,910,319	Jun. 8, 1999	Anderson et al.		
5,922,340	Jul. 13, 1999	Berde et al.		
5,994,544	Nov. 30, 1999	Jones et al.		
6,066,643	May 23, 2000	Perry		
6,046,187	Apr. 4, 2000	Berde et al.		
6,075,020	Jun. 13, 2000	Cincotta et al.		
6,093,821	Jul. 25, 2000	Jones et al.		
6,113,944	Sep. 5, 2000	Pathak et al.		
6,121,450	Sep. 19, 2000	Jones et al.		
6,121,291	Sep. 19, 2000	Gleason		
6,127,365	Oct. 3, 2000	Elliot et al.		

DATE CONSIDERED

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
		Applicant	Jost-Price et al.
STATEMEN	ON DISCLOSURE T BY APPLICANT	Filing Date	February 12, 2004
(Use several sheets if necessary)		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

6,140,337	Oct. 31, 2000	Binder et al.		
6,197,830	Mar. 6, 2001	Frome		•
 6,204,245	Mar. 20, 2001	Siegel et al.		
6,211,171	Apr. 3, 2001	Sawynok et al.		
6,238,702	May 29, 2001	Berde et al.		
6,245,356	Jun. 12, 2001	Baichwal		
 6,245,782	Jun. 12, 2001	Serebruany et al.		
6,258,853	Jul. 10, 2001	Stowell et al.		
6,281,248	Aug. 28, 2001	Ahmed		
6,300,343	Oct. 9, 2001	Steiner		
6,310,250	Oct. 30, 2001	Stowell et al.		
 6,316,672	Nov. 13, 2001	Stowell et al.		
 6,369,051	Apr. 9, 2002	Jenkins		
 6,369,079	Apr. 9, 2000	Rubin et al.		
6,372,763	Apr. 16, 2002	Jenner		
6,380,207	Apr. 30, 2002	Coghlan et al.		
6,380,223	Apr. 30, 2002	Dow et al.		
6,403,120	Jun. 11, 2002	Sherman et al.		
6,403,597	Jun. 11, 2002	Wilson et al.		
 6,419,958	Jul. 16, 2002	Sherman et al.		
6,426,339	Jul. 30, 2002	Berde et al.		
6,436,956	Aug. 20, 2002	Murthy et al.		
6,444,665	Sep. 3, 2002	Helton et al.		
 6,448,405	Sep. 10, 2002	Jones et al.		
 		T T		

DATE CONSIDERED

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
IN ITO DATA TI	ON BIGGI COURT	Applicant	Jost-Price et al.
STATEMEN	ON DISCLOSURE T BY APPLICANT	Filing Date	February 12, 2004
(Use several sheets if necessary)		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

	6,452,054	Sep. 17, 2002	Aronhime et al.			
	6,472,401	Oct. 29, 2002	Kreutner			
	6,482,440	Nov. 19, 2002	Zemlan et al.			
	6,488,960	Dec. 03, 2002	Bardsley			
	6,500,987	Dec. 31, 2002	Schwartz et al.			
	6,503,927	Jan. 07, 2003	Ronsen et al.			
	6,506,766	Jan. 14, 2003	Coghlan et al.			
	6,517,866	Feb. 11, 2003	Am Ende et al.			
-	6,545,057	Apr. 8, 2003	Wang et al.			
-	6,548,084	Apr. 15, 2003	Leonard et al.			
	6,552,014	Apr. 22, 2003	Serebruany et al.			
	6,562,629	May 13, 2003	Lin et al.			
	6,569,463	May 27, 2003	Patel et al.			
	6,570,020	May 27, 2003	Murry et al.			
	6,579,899	Jun. 17, 2003	Wurtman et al.	:		
	6,596,309	Jul. 22, 2003	Einig et al.			
	6,599,529	Jul. 29, 2003	Skinhøj et al.			
	6,627,653	Sep. 30, 2003	Plata-Salaman et al.			
	6,645,523	Nov. 11, 2003	Lemmens et al.			
	6,677,326	Jan. 13, 2004	Bardsley et al.			
	6,683,114	Jan. 27, 2004	Thomasson			
	6,699,893	Mar. 2, 2004	Dow et al.			
	6,897,206	May 24, 2005	Sackeyfio et al.			
	<u> </u>			·	•	

EXAMINER	DATE CONSIDERED
----------	-----------------

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
		Applicant Jost-Price et al.	
STATEMEN	ON DISCLOSURE T BY APPLICANT	Filing Date	February 12, 2004
(Use several sheets if necessary)		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

Ţ	<del></del>	<del></del>		,	-
6,955,815	Oct. 18, 2005	Sackeyfio et al.			
2001/0041802	Nov. 15, 2001	Kym et al.			
2002/0009487	Jan. 24, 2002	Murdock et al.			
2002/0103217	Aug. 1, 2002	Scott et al.			
2002/0107235	Aug. 8, 2002	Liu et al.			
2002/0147336	Oct. 10, 2002	Dow et al.			
2002/0173505	Nov. 21, 2002	Skogvail			
2003/0008844	Jan. 9, 2003	Spero et al.			
2003/0017972	Jan. 23, 2003	Pun et al.			
2003/0073703	Apr. 17, 2003	Coghlan et al.			
2003/0096019	May 22, 2003	Currie et al.			
2003/0120081	Jun. 26, 2003	Murry et al.			
2003/0139698	Jul. 24, 2003	Hyson			
2003/0171585	Sep. 11, 2003	Scott et al.			
2003/0176478	Sep. 18, 2003	Scanlan et al.			
2004/0029860	Feb. 12, 2004	Gil-Ad et al.			
2004/0110734	June 10, 2004	Sackeyfio et al.			
2004/0220153	Nov. 4, 2004	Jost-Price et al.			
2005/0153947	Jul. 14, 2005	Padval et al.			
FOREIG	N PATENT OR P	JBLISHED FOREIGN PATENT A	PPLICATION	ON	
Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
WO 91/02527 A1	Mar. 7, 1991	W.I.P.O.			
WO 93/22685 A1	Nov. 11, 1993	W.I.P.O.			
	2001/0041802 2002/0009487 2002/0103217 2002/0107235 2002/0147336 2002/0173505 2003/0008844 2003/0017972 2003/0073703 2003/0096019 2003/0120081 2003/0171585 2003/0176478 2004/0029860 2004/0110734 2004/0220153 2005/0153947 FOREIGE Document Number WO 91/02527 A1	2001/0041802         Nov. 15, 2001           2002/0009487         Jan. 24, 2002           2002/0103217         Aug. 1, 2002           2002/0107235         Aug. 8, 2002           2002/0147336         Oct. 10, 2002           2002/0173505         Nov. 21, 2002           2003/0008844         Jan. 9, 2003           2003/0017972         Jan. 23, 2003           2003/0073703         Apr. 17, 2003           2003/0120081         Jun. 26, 2003           2003/0139698         Jul. 24, 2003           2003/0171585         Sep. 11, 2003           2003/0176478         Sep. 18, 2003           2004/0029860         Feb. 12, 2004           2004/0110734         June 10, 2004           2004/0220153         Nov. 4, 2004           2005/0153947         Jul. 14, 2005           FOREIGN PATENT OR PRESENT OR	2001/0041802         Nov. 15, 2001         Kym et al.           2002/0009487         Jan. 24, 2002         Murdock et al.           2002/0103217         Aug. 1, 2002         Scott et al.           2002/0107235         Aug. 8, 2002         Liu et al.           2002/0147336         Oct. 10, 2002         Dow et al.           2002/0173505         Nov. 21, 2002         Skogvall           2003/0008844         Jan. 9, 2003         Spero et al.           2003/0017972         Jan. 23, 2003         Pun et al.           2003/0073703         Apr. 17, 2003         Coghlan et al.           2003/0120081         Jun. 26, 2003         Murry et al.           2003/0139698         Jul. 24, 2003         Hyson           2003/0176478         Sep. 11, 2003         Scott et al.           2004/029860         Feb. 12, 2004         Gil-Ad et al.           2004/0110734         June 10, 2004         Sackeyfio et al.           2005/0153947         Jul. 14, 2005         Padval et al.           FOREIGN PATENT OR PUBLISHED FOREIGN PATENT Al           Document Number         Publication Date         Country or Patent Office           WO 91/02527 A1         Mar. 7, 1991         W.I.P.O.	2001/0041802         Nov. 15, 2001         Kym et al.           2002/0009487         Jan. 24, 2002         Murdock et al.           2002/0103217         Aug. 1, 2002         Scott et al.           2002/0107235         Aug. 8, 2002         Liu et al.           2002/0147336         Oct. 10, 2002         Dow et al.           2002/0173505         Nov. 21, 2002         Skogvall           2003/0008844         Jan. 9, 2003         Spero et al.           2003/0017972         Jan. 23, 2003         Pun et al.           2003/0073703         Apr. 17, 2003         Coghlan et al.           2003/0120081         Jun. 26, 2003         Murry et al.           2003/0120081         Jun. 26, 2003         Hyson           2003/0176478         Sep. 11, 2003         Scott et al.           2003/0176478         Sep. 18, 2003         Scanlan et al.           2004/010734         June 10, 2004         Sackeyfio et al.           2004/02153         Nov. 4, 2004         Jost-Price et al.           2005/0153947         Jul. 14, 2005         Padval et al.           FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION Patent Office           WO 91/02527 A1         Mar. 7, 1991         W.I.P.O.	2001/0041802         Nov. 15, 2001         Kym et al.           2002/0009487         Jan. 24, 2002         Murdock et al.           2002/0103217         Aug. 1, 2002         Scott et al.           2002/0107235         Aug. 8, 2002         Liu et al.           2002/0147336         Oct. 10, 2002         Dow et al.           2003/0008844         Jan. 9, 2003         Spero et al.           2003/0017972         Jan. 23, 2003         Pun et al.           2003/0073703         Apr. 17, 2003         Coghlan et al.           2003/0120081         Jun. 26, 2003         Murry et al.           2003/0139698         Jul. 24, 2003         Hyson           2003/0176478         Sep. 11, 2003         Scott et al.           2004/029860         Feb. 12, 2004         Gil-Ad et al.           2004/0220153         Nov. 4, 2004         Jost-Price et al.           2005/0153947         Jul. 14, 2005         Padval et al.           FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION           Document Number         Publication Date         Country or Patent Office         Class         Subclass           WO 91/02527 A1         Mar. 7, 1991         W.I.P.O.         Class         Subclass

EXA	184	INE	P

DATE CONSIDERED

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
1150011171		Applicant	Jost-Price et al.
STATEMEN	ON DISCLOSURE T BY APPLICANT	Filing Date	February 12, 2004
(Use several sheets if necessary)		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

WO 95/31722 A1	Nov. 23, 1995	W.I.P.O.			
WO 97/10815 A1	Mar. 27, 1997	W.I.P.O.			
WO 98/02169 A1	Jan. 22, 1998	W.I.P.O.			
WO 99/01121 A1	Jan. 14, 1999	W.I.P.O.			
WO 99/59598 A1	Nov. 25, 1999	W.I.P.O.			
WO 00/51592 A1	Sep. 8, 2000	W.I.P.O.			
WO 00/64441 A2	Nov. 2, 2000	W.I.P.O.			
WO 00/66522 A1	Nov. 9, 2000	W.I.P.O.			
WO 01/11334 A2	Feb. 15, 2001	W.I.P.O.			
 WO 02/078643 A2	Oct. 10, 2002	W.I.P.O.			
WO 02/085297 A2	Oct. 31, 2002	W.I.P.O.			
WO 02/43652 A2	Jun. 6, 2002	W.I.P.O.			
 WO 03/002129 A1	Jan. 9, 2003	W.I.P.O.			
WO 03/006026 A1	Jan. 23, 2003	W.I.P.O.			
 WO 04/004734 A1	Jan. 15, 2004	W.I.P.O.			
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)					
Allan et al., "Anti-Emetic Efficacy of Dexamethasone in Combination for Out-Patients Receiving Cytotoxic Chemotherapy," Cancer Chemother. Pharmacol. 18(1):86-87 (1986).					
Ardid and Guilbaud, "Antinociceptive Effects of Acute and 'Chronic' Injections of Tricyclic Antidepressant Drugs in a New Model of Mononeuropathy in Rats," Pain 49(2):279-287 (1992).					
Arnold et al., "A Randomized, Placebo-Controlled, Double-Blind, Flexible-Dose Study of Fluoxetine in the Treatment of Women with Fibromyalgia," Am. J. Med. 112(3):191-197 (2002).					
Ash et al., "The Effects of Dothiepin on Subjects With Rheumatoid Arthritis and Depression," Rheumatology 38(10):959-967 (1999).					
Barden, "Regulation of Corticosteroid Receptor Gene Expression in Depression and Antidepressant Action," J. Psychiatry Neurosci. 24(1):25-39 (1999).					

EXAMINER	DATE CONSIDERED
	if yet in any factor and not assert depart. Include come of this

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
WIEGE METICAL PLACE COLUMN		Applicant	Jost-Price et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Filing Date	February 12, 2004
		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

Beers et al., "Rheumatoid Arthritis," <u>Merck Manual of Medical Information</u> , 2 <sup>nd</sup> ed., Merck Research Laboratories: Whitehouse Station, NJ, pp. 1-7 (2003).
Berberian et al., "The Addition of Topical Doxepin to Corticosteroid Therapy: An Improved Treatment Regimen for Atopic Dermatitis," Int. J. Dermatol. 38(2):145-148 (1999).
Bianchi et al., "Effects of Chlomipramine and Fluoxetine on Subcutaneous Carrageenin-Induced Inflammation in the Rat," Inflamm. Res. 44:466-469 (1995).
Bird and Broggini, "Paroxetine Versus Amitriptyline for Treatment of Depression Associated with Rheumatoid Arthritis: A Randomized, Double Blind, Parallel Group Study," J. Rheumatol. 27:2791-2797 (2000).
Bonuccelli et al., "Amitriptyline and Dexamethasone Combined Treatment in Drug-Induced Headache," Cephalalgia 16(3):197-200 (1996).
Budziszewska et al., "Antidepressant Drugs Inhibit Glucocorticoid Receptor-Mediated Gene Transcription - A Possible Mechanism," <i>Br. J. Pharmacol.</i> 130:1385-1393 (2000).
Calvo et al., "Pharmacokinetics of Amoxapine and Its Active Metabolites," Int. J. Clin. Pharmacol. Ther. Toxicol. 23(4):180-185 (1985).
Cantini et al., "Fluoxetin Combined with Cyclobenzaprine in the Treatment of Fibromyalgia," <i>Minerva Med.</i> 85(3):97-100 (1994). (English Abstract)
Carelli et al., "Silicone Microspheres for pH-Controlled Gastrointestinal Drug Delivery," Int. J. Pharmaceutics 179: 73-83 (1999).
Castanon et al., "Effects of Antidepressants on Cytokine Production and Actions," <i>Brain Behavior Immun</i> . 16:569-574 (2002).
Chan and Lee, "Serotonin Uptake and Imipramine Binding in Rat Platelets After Chronic Dexamethasone and Amitriptyline Treatment," <i>Pharmacol. Res. Comm.</i> 17(7):619-632 (1985).
Chuck et al., "The Effects of Dothiepin on Subjects with Rheumatoid Arthritis and Depression," Rheumatology 39:1425-1426 (2000).
Clark, "Chronic Pain, Depression, and Antidepressants: Issues and Relationships," Johns Hopkins Arthritis website: http://www.hopkins-arthritis.som.jhmi.edu/mngmnt/depression.html
Clouse et al., "Antidepressant Therapy in 138 Patients with Irritable Bowel Syndrome: A Five-Year Clinical Experience," <i>Aliment Pharmacol. Ther.</i> 8(4):409-416 (1994).
Coupet et al., "The Effects of 2-Chloro-11-(4-methyl-1-piperazinyl)-dibenz[b,f] [1,4]oxazepine (Loxapine) and Its Derivatives on the Dopamine-Sensitive Adenylate Cyclase of Rat Striatal Homogenates," <i>Brain Research</i> 116:177-180 (1976).
D'Arcy et al., "Sustained-Release Formulation of Prednisolone Administered Orally to Man," J. Pharm. Sci. 60(7):1028-1033 (1971).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation form with the next communication to applicant.	n if not in conformance and not considered. Include copy of this

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
WEODWIE ON BIRD ON DE		Applicant	Jost-Price et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Filing Date	February 12, 2004
		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

Dessein et al., "Oral Low-Dose Glucocorticosteroids as Compared with Intravenous Methylprednisolone Pulses in the Treatment of Rheumatoid Arthritis," <i>Rheumatology</i> 38(12):1304-1305 (1999).
Didonato et al., "Molecular Mechanisms of Immunosuppression and Anti-Inflammatory Activities by Glucocorticoids," <i>Am. J. Respir. Crit. Care Med.</i> 154:S11-S15 (1996).
Dinan et al., "Dexamethasone Augmentation in Treatment-Resistant Depression," <i>Acta Psychiatr. Scand.</i> 95(1):58-61 (1997).
Drake and Millikan, "The Antipruritic Effect of 5% Doxepin Cream in Patients with Eczematous Dermatitis," Arch. Dermatol. 131(12):1403-1408 (1995).
Drake et al., "Pharmacokinetics of Doxepin in Subjects with Pruritic Atopic Dermatitis," J. Am. Acad. Dermatol. 41(2):209-214 (1999).
el-Mahdy et al., "Antinociceptive and Anti-Inflammatory Activity of a Novel Quipazine Derivative (AAL-13): a Selective Inhibitor of 5-Hydroxytryptamine Reuptake," <i>J. Pharm. Pharmacol.</i> 42(7):522-524 (1990).
Ehrenstein, "Combination Therapy in Rheumatoid Arthritis," Br. J. Rheumatol. 34(6):580-581 (1995).
Esposito et al., "Production of Eudragit Microparticles by Spray-Drying Technique: Influence of Experimental Parameters on Morphological and Dimensional Characteristics," <i>Pharm. Dev. Technol.</i> 5(2):267-278 (2000).
Fishbain, "Evidence-Based Data on Pain Relief With Antidepressants," Ann. Med. 32:305-316 (2000).
Fowler et al., "Imipramine, Rheumatoid Arthritis and Rheumatoid Factor," Curr. Med. Res. Opin. 5(3):241-246 (1977).
Frank et al., "Antidepressant Analgesia in Rheumatoid Arthritis," J. Rheumatol. 15(11):1632-1638 (1988).
Godefroy et al., "Do Acute or Chronic Tricyclic Antidepressants Modify Morphine Antinociception in Arthritic Rats?" Pain 25:233-244 (1986).
Goldenberg et al., "A Randomized, Double-Blind Crossover Trial of Fluoxetine and Amitriptyline in the Treatment of Fibromyalgia," <i>Arthritis Rheum.</i> 39(11):1852-1859 (1996).
Goodnick et al., "Sertraline in Coexisting Major Depression and Diabetes Mellitus," <i>Psychopharmacol. Bull.</i> 33(2):261-264 (1997).
Gruber et al., "The Management of Treatment-Resistant Depression in Disorders on the Interface of Psychiatry and Medicine. Fibromyalgia, Chronic Fatigue Syndrome, Migraine, Irritable Bowel Syndrome, Atypical Facial Pain, and Premenstrual Dysphoric Disorder," <i>Psychiatr. Clin. North Am.</i> 19(2):351-369 (1996).
Guenther, "Tazarotene Combination Treatments in Psoriasis," J. Am. Acad. Dermatol. 43:S36-S42, 2000.
Gupta et al., "Antidepressant Drugs in Dermatology. An Update," Arch. Dermatol. 123(5):647-652 (1987).

DATE CONSIDERED

	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
		Applicant	Jost-Price et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Filing Date	February 12, 2004
		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

Gupta and Gupta, "The Use of Antidepressant Drugs in Dermatology," J. Eur. Acad. Dermatol. Venereol. 15(6):512-518 (2001).
Hammad and Müller, "Increasing Drug Solubility by Means of Bile Salt-Phosphatidylcholine-Based Mixed Micelles," Eur. J. Pharm. Biopharm. 46:361-367 (1998).
Healey and Wilske, "Evaluating Combination Drug Therapy in Rheumatoid Arthritis," J. Rheumatol. 18(5):641-642 (1991).
Hinze-Selch et al., "Effects of Antidepressants on Weight and on the Plasma Levels of Leptin, TNF-α and Soluble TNF Receptors: A Longitudinal Study in Patients Treated with Amitriptyline or Paroxetine," Neuropsychopharmacology 23(1):13-19 (2000).
Holsboer, "The Corticosteroid Receptor Hypothesis of Depression," Neuropsychopharmacology 23(5):477-501 (2000).
Inouye et al., "Sustained Release Tablets Based on Chitosan and Carboxymethylcellulose Sodium," <i>Drug Des. Deliv.</i> 1:297-305 (1987).
Jett et al., "The Effects of Mexiletine, Desipramine and Fluoxetine in Rat Models Involving Central Sensitization," Pain 69(1-2):161-169 (1997).
Johnson, "Fluoxetine and Amitriptyline in the Treatment of Fibromyalgia," J. Fam. Pract. 44(2):128-130 (1997).
Jue et al., "Amoxapine: A Review of Its Pharmacology and Efficacy in Depressed States," Drugs 24:1-23 (1982).
Karlsten and Gordh, "How Do Drugs Relieve Neurogenic Pain?" Drugs Aging 11(5):398-412 (1997).
Kirwan and Lim, "Low Dose Corticosteroids in Early Rheumatoid Arthritis. Can These Drugs Slow Disease Progression?" <i>Drugs Aging</i> 8(3):157-161 (1996).
Kirwan, "Systemic Low-Dose Glucocorticoid Treatment in Rheumatoid Arthritis," Rheum. Dis. Clin. North Am. 27(2):389-403 (2001).
Kitamori and Makino, "Effect of Drug Content and Drug Particle Size on the Change in Particle Size During Tablet Compression," J. Pharm. Pharmacol. 31:505-507 (1979).
Koh et al., "Low Dose Amitriptyline in Ankylosing Spondylitis: A Short Term, Double Blind, Placebo Controlled Study," J. Rheumatol. 24(11):2158-2161 (1997).
Kristensen, "Plasma Protein Binding of Imipramine in Patients with Rheumatoid Arthritis," Eur. J. Clin. Pharmacol. 28:693-696 (1985).
Kubera et al., "Effect of Repeated Desipramine and Fluoxetine Administration on Post-Adjuvant Arthritis," Pol. J. Pharmacol. 52(3):229-235 (2000).
Kubera et al., "Anti-Inflammatory Effects of Antidepressants Through Suppression of the Interferon-γ /Interleukin-10 Production Ratio," J. Clin. Psychopharmacol. 21(2):199-206 (2001).

DATE CONSIDERED

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No.	50164/026005
(MODIFIED)	PATENT AND TRADEMARK OFFICE		10/777,517
11.500.41.501.01.001.001.001		Applicant	Jost-Price et al.
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Filing Date	February 12, 2004
		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

 •
Lanquillon et al., "Cytokine Production and Treatment Response in Major Depressive Disorder," Neuropsychopharmacology 22(4):370-379 (2000).
Lee and Chan, "Effect of Steroids on the Inhibition of Platelet 5HT Uptake by Desipramine and Other Antidepressants," Eur. J. Pharmacol. 106(2):255-262 (1985).
Linden et al., "Psoriasis: Current Perspectives with an Emphasis on Treatment," Am. J. Med. 107:595-605, 1999.
Lydiard and Gelenberg, "Amoxapine - An Antidepressant with Some Neuroleptic Properties? A Review of Its Chemistry, Animal Pharmacology and Toxicology, Human Pharmacology, and Clinical Efficacy," Pharmacotherapy 1(3):163-178 (1981).
Macfarlane et al., "Trimipramine in Rheumatoid Arthritis: A Randomized Double-Blind Trial in Relieving Pain and Joint Tenderness," Curr. Med. Res. Opin. 10(2):89-93 (1986).
MacNeill and Dick, "Imipramine and Rheumatoid Factor," J. Int. Med. Res. 4(2 Suppl):23-27 (1976).
Maes et al., "Lower Serum Activity of Prolyl Endopeptidase in Fibromyalgia is Related to Severity of Depressive Symptoms and Pressure Hyperalgesia," <i>Psychol. Med.</i> 28(4):957-965 (1998).
Maes, "Major Depression and Activation of the Inflammatory Response System," <a href="Cytokines">Cytokines</a> , Stress, and <a href="Depression">Depression</a> , Ed: Dantzer et al., Plenum Publishers, NY, pp. 25-46 (1999).
Maes et al., "Negative Immunoregulatory Effects of Antidepressants: Inhibition of Interferon-gamma and Stimulation of Interleukin-10 Secretion," Neuropsychopharmacology 20(4):370-379 (1999).
Maes et al., "Effects of Atypical Antipsychotics on the Inflammatory Response System in Schizophrenic Patients Resistant to Treatment with Typical Neuroleptics," Eur. Neuropsychopharmacol. 10:119-124 (2000).
Magni, "The Use of Antidepressants in the Treatment of Chronic Pain. A Review of the Current Evidence," <i>Drugs</i> 42(5):730-748 (1991).
Martelli et al., "Mechanism of Inhibition of Experimental Inflammation by Antidepressant Drugs," Eur. J. Pharmacol. 2(3):229-233 (1967).
Mastaglia, "Adverse Effects of Drugs on Muscle," Drugs 24:304-321 (1982).
 McBride et al., "Management of Rheumatoid Arthritis," South. Med. J. 62:307-314 (1969).
 McLain, "Rheumatoid Arthritis - Update on New Therapies," South. Med. J. 94(9):893-895 (2001).
The Merck Index, Monograph Numbers 04972 and 03712.
The Merck Manual, Section 4, Chapter 44, Asthma.
Michelson et al., "Imipramine Reduces the Local Inflammatory Response to Carrageenin," Agents Actions 42:25-28 (1994).

EXAMINER	DATE CONSIDERED
EVAMINED: Initial situation considered De-	uline through eitation if not in conformance and not considered. Include convert this

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50164/026005
		Serial No.	10/777,517
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant	Jost-Price et al.
		Filing Date	February 12, 2004
		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

Mitra, "Role of Anti-Depressant Fluoxetine in the Puva Treatment of Psoriasis Vulgaris," <i>Ind. J. Dermatol.</i> 67:292- 293, 2001
Morris, "Combination Drug Therapy in Rheumatoid Arthritis," J. Rheumatol. 24(4):803-804 (1997).
Okugawa et al., "Long-Term Treatment with Antidepressants Increases Glucocorticoid Receptor Binding and Gene Expression in Cultured Rat Hippocampal Neurones," <i>J. Neuroendocrinol.</i> 11:887-895 (1999).
Papp et al., "Sertraline for Chronic Obstructive Pulmonary Disease and Comorbid Anxiety and Mood Disorders," Am. J. Psychiatry 152(10):1531 (1995).
Pariante et al., "Steroid-Independent Translocation of the Glucocorticoid Receptor by the Antidepressant Desipramine," <i>Mol. Pharmacol.</i> 52:571-581 (1997).
PDR <sup>®</sup> Electronic Library TM Entry for Paxil <sup>®</sup> (Paroxetine Hydrochloride).
Petitto et al., "Improvement of Arthritis with Fluoxetine," Psychosomatics 33(3):338-341 (1992).
Pfeiffer, "Drugs for Pain in the Elderly," <i>Geriatrics</i> 37(2):67-69, 73, 76 (1982).
Pullar, "Combination Therapy in Rheumatoid Arthritis," <i>Br. J. Rheumatol.</i> 30(4):311 (1991).
Puttini et al., "A Comparison of Dothiepin Versus Placebo in the Treatment of Pain in Rheumatoid Arthritis and the Association of Pain With Depression," <i>J. Int. Med. Res.</i> 16(5):331-337 (1988).
Rani et al., "An Evaluation of Antidepressants in Rheumatic Pain Conditions," <i>Anesth. Analg.</i> 83:371-375 (1996).
Rao et al., "Controlled and Complete Release of a Model Poorly Water-Soluble Drug, Prednisolone, from Hydroxypropyl Methylcellulose Matrix Tablets Using (SBE) <sub>7m</sub> -β-Cyclodextrin as a Solubilizing Agent," <i>J. Pharm. Sci.</i> 90(7):807-816 (2001). (abstract only)
Russell and Ramos-Remus, "Combination Drug Therapy in Rheumatoid Arthritis," <i>J. Rheumatol.</i> 24:803-804 (1997).
Sabroe et al., "The Effects of Topical Doxepin on Responses to Histamine, Substance P and Prostaglandin E2 in Human Skin," <i>Br. J. Dermatol.</i> 137(3):386-390 (1997).
Schreiber et al., "The Antinociceptive Effect of Fluvoxamine," Eur. Neuropsychopharmacol. 6(4):281-284 (1996).
Scott et al., "Use of Transdermal Amitriptyline Gel in a Patient with Chronic Pain and Depression," Pharmacotherapy 19(2):236-239 (1999).
Shelanski et al., "Evaluation of Cutaneous Reactivity to Recently Marketed Dermatologic Products," Int. J. Dermatol. 35(2):137-140 (1996).
Slaughter et al., "Clinical Outcomes Following a Trial of Sertraline in Rheumatoid Arthritis," <i>Psychosomatics</i> 43(1):36-41 (2002).
C - F - F - F - F - F - F + S - F ( - S + - S - S - S - S - S - S - S - S -

EXAMINER	DATE CONSIDERED
EYAMINER: Initial citation considered. Draw line through citation	if not in conformance and not considered. Include conv of this

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	50164/026005
		Serial No.	10/777,517
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant	Jost-Price et al.
		Filing Date	February 12, 2004
		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

Slotkin et al., "Do Glucocorticoids Contribute to the Abnormalities in Serotonin Transporter Expression and Function Seen in Depression? An Animal Model," <i>Biol. Psychiatry</i> 40(7):576-584 (1996).
Smith and Correlli, "Doxepin in the Management of Pruritus Associated with Allergic Cutaneous Reactions," <i>Ann. Pharmacother.</i> 31(5):633-635 (1997).
 Swinson, "Antidepressant Therapy and Rheumatoid Arthritis," J. Rheumatol. 17:277 (1990).
Tangri et al., "Anti-inflammatory Activity of Imipramine and Congeners," Biochem. Pharmacol. 15:825-831 (1966).
Tasset and Pesce, "Amoxapine in Human Overdose," J. Anal. Toxicol. 8(3):124-128 (1984).
Thorpe and Marchant-Williams, "The Role of an Antidepressant, Dibenzepin (Noveril), in the Relief of Pain in Chronic Arthritic States," <i>Med. J. Austral.</i> 1(8):264-266 (1974).
Uekama et al., "Improvement of Oral Bioavailability of Prednisolone by β-Cyclodextrin Complexation in Humans," J. Pharm. Dyn. 6:124-127 (1983).
van den Berg et al., "Role of Tumour Necrosis Factor α in Experimental Arthritis: Separate Activity of Interleukin 1β in Chronicity and Cartilage Destruction," <i>Ann. Rheum. Dis.</i> 58(Suppl I):I40-I48 (1999).
Van Laethem et al., "A Novel Aspect of the Anti-Inflammatory Actions of Glucocorticoids: Inhibition of Proximal Steps of Signaling Cascades in Lymphocytes," Cell. Mol. Life Sci. 58:1599-1606 (2001).
Vedder et al., "Regulation of Glucocorticoidreceptor-mRNA in Human Blood Cells by Amitriptyline and Dexamethasone," <i>J. Psych. Res.</i> 33:303-308 (1999).
Williams, "Combination Second-Line Therapy for Rheumatoid Arthritis," Br. J. Rheumatol. 33:603-604 (1994).
Wolfe et al., "A Double-Blind Placebo Controlled Trial of Fluoxetine in Fibromyalgia," Scand. J. Rheumatol. 23(5):255-259 (1994).
Xia et al., "Tricyclic Antidepressants Inhibit IL-6, IL-1β and TNF-α Release in Human Blood Monocytes and IL-2 and Interferon-γ in T Cells," <i>Immunopharmacology</i> 34(1):27-37 (1996).
Yano et al., "Preparation of Prednisolone-Appended $\alpha$ -, $\beta$ - and $\gamma$ -Cyclodextrins: Substitution at Secondary Hydroxyl Groups and <i>In Vitro</i> Hydrolysis Behavior," <i>J. Pharm. Sci.</i> 90(4):493-503 (2001).
Yano et al., "Colon-Specific Delivery of Prednisolone-Appended α-Cyclodextrin Conjugate: Alleviation of Systemic Side Effect After Oral Administration," <i>J. Control. Rel.</i> 79(1-3):103-112 (2002).
Yaron et al., "Fluoxetine and Amitriptyline Inhibit Nitric Oxide, Prostaglandin E <sub>2</sub> , and Hyaluronic Acid Production in Human Synovial Cells and Synovial Tissue Cultures," <i>Arth. Rheumatol.</i> 42(12):2561-2568 (1999).
Yocum, "T Cells: Pathogenic Cells and Therapeutic Targets in Rheumatoid Arthritis," Sem. Arth. Rheumat. 29(1):27-35 (1999).

EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.	

Sheet <u>13</u> of <u>13</u>

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE	Attorney Docket No. 50164/026005	50164/026005
	PATENT AND TRADEMARK OFFICE	Serial No.	10/777,517
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant	Jost-Price et al.
		Filing Date	February 12, 2004
		Group	1614
(37 C.F.R. § 1.98(b))		IDS Filed	December 20, 2007

Yohannes et al., "A Feasibility Study of Antidepressant Drug Therapy in Depressed Elderly Patients with Chronic Obstructive Pulmonary Disease," <i>Int. J. Geriatr. Psychiatry</i> 16(5):451-454 (2001).
 International Search Report for WO 04/030618 dated January 10, 2005.